

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:

All Actions

No. 1:19-md-2875-RBK

Hon. Robert B. Kugler
Hon. Thomas I. Vanaskie

**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO COMPEL
AND PLAINTIFFS' CROSS-MOTION FOR A PROTECTIVE ORDER**

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I. INTRODUCTION

More than a year after the close of formal fact discovery (D.E. 864), and more than two years after Plaintiffs were Court-ordered to issue all subpoenas to third-parties (D.E. 575), the Defendants are, only now, attempting to seek discovery via a Rule 45 subpoena from an irrelevant pharmacy which has nothing to do with the products, claims or issues in this case. As the well-developed factual record shows, at no point have Plaintiffs or Defendants sought testimony about Valisure (or the findings contained within its Citizen Petition from 2019). Defendants' dilatory request is made even more prejudicial by the fact that since the formal close of fact discovery, the Parties have fully briefed issues related to general causation, Class Certification, and have exchanged liability expert reports related to the underlying merits issue in this case.

Defendants claim that the information they seek from Valisure is somehow germane to probing the reliability of Plaintiffs' experts (notably, Dr. Ron Najafi), but this argument is without merit, and contrary to the actual expert discovery Defendants are pursuing in depositions of Plaintiffs' liability experts. As it relates specifically to Dr. Najafi, Defendants have already sought (and received), any and all information that might bear upon the reliability of his expert methodology that could be found within his own possession, custody and control. The internal testing or documentation conducted by a third-party (whose findings are already

memorialized and delineated in a Citizen Petition publicly available since 2019), has no bearing whatsoever to the reliability of Plaintiffs' remaining experts and should play no role in the *Daubert* analysis. Moreover, given Valisure's checkered past, Plaintiffs will experience real and cognizable harm in expending time, money and resources assessing whatever documents might be produced by this subpoena, and attempting to assess the credibility of the laboratory.

In light of the posture of this litigation, Plaintiffs request that the Court deny the Defendants' motion to compel and issue a protective order quashing the subpoena *duces tecum* to Valisure (hereafter "Valisure Subpoena") attached as Exhibit A.

II. FACTUAL BACKGROUND

On December 14, 2022, Defendant ZHP provided notice that they were serving a subpoena on Valisure. Valisure subsequently objected to the subpoena on December 28, 2022, on the grounds that it was untimely, and indicated it would not produce documents. Plaintiffs met and conferred with Defendants on December 28, 2022, and again on January 3, 2022.

As Plaintiffs articulated to Defendants on their meet-and-confer, fact discovery in this litigation ended over a year ago, on August 2, 2021. *See* D.E. 864. Additionally, more than two years ago, Plaintiffs were ordered by the Court to serve any and all subpoenas they intended to serve upon third parties by October 15, 2020. D.E. 575. The subpoenas Plaintiffs issued on October 15, 2020, were subject to

extensive and protracted briefing by the Parties. *See* D.E. 652, *et. seq.* During that protracted briefing, the Parties met and conferred countless times, and the Court heard hours of oral argument regarding third-party discovery.

For their part, Defendants have taken third-party discovery from almost sixty (60) physicians and TPPs. This discovery was initiated by Defendants in advance of the August 2021 deadline. They rightly have not pursued any other third-party discovery since, until now.

III. LEGAL STANDARD

“A Rule 45 subpoena must fall within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1).” *Schmulovich v. 1161 Rt. 9 LLC*, 2007 U.S. Dist. LEXIS 59705 at *2 (D.N.J. Aug.15, 2007). Although discovery is “undeniably broad, there are limits to the permissible scope of discovery.” *Koninklijke Philips N.V. v. Hunt Control Sys., Inc.*, 2014 U.S. Dist. LEXIS 52347, at *2 (D.N.J. Apr. 16, 2014); *see also Raritan Bay Fed. Credit Union v. CUMIS Ins. Soc’y, Inc.*, 2010 U.S. Dist. LEXIS 112640, at *10 (D.N.J. Oct. 21, 2010). The relevancy standard “is not so liberal as to allow a party to roam in shadow zones of relevancy and to explore matter which does not appear germane merely on the theory that it might become so.” *Id.* at *6. Courts also have inherent discretion to enforce their own scheduling and case management orders, such as the Court’s prior case management orders here that required the parties to complete all fact discovery more than one year ago.

a. The Court has Inherent Discretion to Issue a Protective Order Quashing a Subpoena

The Court is entitled to issue a protective order if the requesting party demonstrates either that the requested discovery does not fall within Rule 26, or that the requested discovery imposes an unreasonable burden, or is otherwise interposed for purposes of harassment or undue delay. Fed. R. Civ P. 26(b)(2)(C)(iii).

i. The Court Can *Sua Sponte* Quash the Subpoena for Being Untimely

If the subpoena is deemed untimely, even without this instant motion the Court has the authority to quash the subpoena even without motion.¹ This authority is also rooted in Fed. R. Civ. P. 16(f) which authorizes a district court to issue, *sua sponte*, “any just orders ... if a party or its attorney ... fails to obey a scheduling or other pretrial order.” *Mulero-Abreu v. P.R. Police Dep’t*, 675 F.3d 88, 91 (1st Cir. 2012) (citing Fed. R. Civ. P. 16(f)(1)(C)).

¹ See *Galloway v. Islands Mech. Contractor, Inc.*, Civil Action No. 2008-071, 2013 U.S. Dist. LEXIS 5232, at *12 (D.V.I. Jan. 14, 2013); see, also, *McNerney v. Archer Daniels Midland Co.*, 164 F.R.D. 584, 588 (W.D.N.Y. 1995) (opining that even if a party does not have standing to object to a subpoena issued to a third-party witness, a more “fundamental problem[]” with the subpoena arises when the opposing party “is seeking to conduct discovery after the deadline for completing discovery has passed” and, under those circumstances, “the subpoenas and discovery requests should be denied.”).

ii. The Court Can *Sua Sponte* Quash the Subpoena for Being Irrelevant

If the information requested by a subpoena does not meet the baseline Rule 26 standard of relevance, the Court must issue a protective order quashing such a subpoena without further inquiry. *See Cooper Health System v. Virtua Health, Inc.*, 259 F.R.D. 208, 216 (D.N.J. 2009) (motion for protective order granted where discovery sought had nothing to do with the issues in the case and requesting party's hope that responses to non-relevant requests may contain relevant information does not justify an improper request); *Raritan Baykeeper, Inc. v. NL Industries Inc.*, Civ. No. 09-4117 2014 WL2965881 *7 (D.N.J. July 1, 2014) (discovery requests improper because they had "no relevance" to any element of the claim plaintiff must prove).

IV. ARGUMENT

a. Plaintiffs Have Standing to Seek a Protective Order Quashing the Valisure Subpoena

Despite not having been the recipient of the subpoena, Plaintiffs have standing under Rule 26 to move for a protective order to enjoin the production of irrelevant information for subpoenas issued to non-party. *Aetrex Worldwide, Inc. v. Burten Distrib., Inc.*, 2014 U.S. Dist. LEXIS 172857, at *5 (D.N.J. Dec. 15, 2014); *see also In re Actiq Sales & Mktg. Practices Litig.*, 2011 U.S. Dist. LEXIS 130153, at *3 (W.D. Pa. Nov. 10, 2011) ("The explicit mention of a 'party' in [Fed.R.Civ.P. 26(c)]

has been interpreted to provide standing for a party to contest discovery sought from third-parties.”).

b. The Valisure Subpoena is Untimely

There can be no dispute that Defendants’ subpoena to Valisure is untimely. This Court ordered that Plaintiffs were required to issue all subpoenas on October 15, 2020, and that all depositions of third parties were to be completed when the second (and final) wave of discovery was to be completed on August 15, 2021.

Defendants cannot credibly claim that this subpoena was only served now because the information it seeks was unknown to them until December of 2022. The Citizen Petition that forms the foundation of this subpoena was submitted (and published to the public domain) on June 13, 2019. Defendants consequently had more than two years to subpoena records from Valisure, to the extent they believed such records were somehow necessary for their claims and defenses. Instead, Defendants opted to subpoena this entity forty-five (45) days after Plaintiffs submitted their expert liability reports, three-hundred and ninety-nine (399) days after Plaintiffs submitted their motion for Class Certification, and four-hundred and eighty-six (486) days after the close of fact discovery.

Defendants’ own document productions (completed prior to the close of fact discovery), likewise undercut the Defendants’ hyperbolic sense of urgency contained within their motion. Defendants were made aware of the existence of this

Valisure Citizen's petition in June of 2019. *See, e.g.*, TORRENT-MDL2875-00403743 (attached as Exhibit B), APL-MDL-2875-0692978 (attached as Exhibit C), MYLAN-MDL2875-00415142 (attached as Exhibit D), ZHP02168433 (attached as Exhibit E), TEVA-MDL2875-00495936 (attached as Exhibit F).

Defendants' self-inflicted wounds in not requesting this information in a timely manner (when the Valisure Citizen Petition has been known to them during the entire lifespan of this MDL) does not warrant the unprecedented re-opening of fact discovery in this litigation. For this reason alone the Court should quash the Valisure Subpoena.

c. The Untimely Valisure Subpoena Does Not Even Meet the Baseline Requirements of Rule 26

It is without question that under Rule 26, the discovery must be relevant. While normally a court must make its best guess as to relevance, in this case the Court has the benefit of hundreds hours of deposition testimony, millions of pages of document production, and thousands of pages of briefing and exhibits to determine whether testing conducted by this laboratory is relevant.

Upon review of the full factual record developed in this case at this juncture (which, again, has now been closed for some time), the Court can come to no other conclusion that than this: internal information related to Valisure's Valsartan testing is completely untethered from the litigation. First, at no point during the hundreds of hours of factual depositions and 30(b)(6) testimony did any party so much as ask

a question about Valisure, which demonstrates that Valisure's testing has no bearing on any claims any Plaintiff in this litigation is making. If the Defendants were somehow trying to argue that Valisure's June 2019 Citizen Petition was relevant to a potential defense, it is belied by the fact that the Defendants did not explore this possibility in any of the discovery they conducted, prior to now. Should they even more preposterously argue try to argue that this subpoena is relevant to the TPP specific litigation, Defendants did not so much as request any documents related to Valisure in their Rule 34 document requests to the Plaintiffs, in the subpoenas issued by the Defendants to SummaCare, Humana or Emblem in 2021, or in any of the subsequent TPP specific discovery propounded in the summer of 2022.

i. The Requested Documents are Immaterial and Irrelevant to the *Daubert* Assessment of Plaintiffs' Experts

While Defendants' motion argues that this Valisure information is necessary to conduct a comprehensive *Daubert* analysis of Plaintiffs' experts, nothing within the *Daubert* case law permits the kind of wide-ranging inquiry into the internal testing conducted by a third party (unrelated to an expert) as a means to test that expert's reliability.

ii. Any Marginally Relevant Information Related to Plaintiffs' Expert Dr. Najafi Has Been Produced

Defendants argue that Dr. Najafi's contract testing for Valisure somehow renders the internal information within Valisure's exclusive possession and custody relevant. However, Defendants' citations to the Special Master's order related to

Dr. Najafi's production of documents have no weight as it relates to the relevance of Valisure third-party discovery. Defendants' basis for the documents that were the subject of their previous Motion to Compel (related to Dr. Najafi) (hereafter "Najafi MTC") was that information about potential testing conducted by Dr. Najafi *himself* was necessary in order to question and probe the reliability of Dr. Najafi's *own* methods and opinions. The Court agreed, and ordered production of these documents. Plaintiffs completed that production in August of this year.

iii. The Reliability of an Expert Cannot be Questioned on the Basis of Third-Party Internal Documents

However, having received an inch, Defendants now are poised to try and take this argument for a mile and argue that Dr. Najafi (and all of Plaintiffs' liability experts) must be probed on the internal documents within the possession custody and control of Valisure. Defendants' brief lacks any legal authority to support the proposition that internal documents related to a company for which an expert did not rely upon (let alone has never even once seen and could not access in the public domain), can somehow be used to probe the reliability of that expert.

As to Dr. Najafi, it matters not that he once had a contract with Valisure with a limited scope of engagement – he cannot be bound by Valisure's documents which he has not seen, and are not within his possession, custody or control. Were this discovery permissible as part of the *Daubert* analysis, and were the shoe on the other foot, Plaintiffs would be permitted to seek documents from every Postdoctoral

scholar supervised by ZHP's expert Dr. Fengtian Xue or SOPs from every pharmaceutical company consulted by Dr. Afnan. But the reality is that *Daubert* does not permit such a wide and free-ranging inquiry into information outside of the public domain or expert's possession. Defendants have already asked for, and received, documents in Dr. Najafi's possession, custody and control on this very point. They are free to question him on those documents in the context of his expert opinion, along with the publicly filed Citizen Petition produced in this litigation. However, documents which Dr. Najafi has not relied upon (let alone even seen with his eyes), are completely immaterial to his opinions and report. This is even more true for the remaining Plaintiffs' liability experts, who did not even so much as have a limited contractual relationship with Valisure.

iv. Defendants Have Not Even Questioned Plaintiffs' Experts About the Valisure Citizen's Petition at Issue in the Subpoena

Defendants' overall argument that the documents related to the Valisure Citizen Petition are necessary to question the validity of *all* the Plaintiffs' experts is completely undermined by the actual discovery taken by Defendants thus far of Plaintiffs' liability experts. To wit: Defendants have not even used the original document which forms the basis of this request – the Valisure Citizen Petition – as an exhibit in any of the five (5) depositions of Plaintiffs' liability experts Defendants

have taken thus far.² As such, Defendants cannot be taken at face value when they claim to the Court that these documents are necessary to “fairly test the validity of the [Dr. Plunkett’s] report[.]” when they did not even attempt to question Dr. Plunkett about the publicly available Valisure Citizen Petition produced by them in this litigation, and at issue in their subpoena.

d. A Protective Order is Necessary to Prevent Prejudice to the Plaintiffs

The Court should issue a protective order quashing the subpoena to prevent the Plaintiffs from experiencing real and cognizable harm and prejudice should the Defendants be permitted to take discovery from Valisure.

i. The Litigation Has Proceeded Forward with Expediency Since Discovery Closed

In terms of the timing, it is not just that the Defendants are seeking to re-open fact discovery well after the Court ordered it be closed – it is that since discovery closed, the Parties have practically litigated the entire case during this time. Indeed, since August 2021, the Parties have engaged³ in the following substantive briefing and case management events:

² At the filing of this brief Defendants have completed depositions of the following liability experts (Russ, Craft, Panagos, Plunkett and Hecht).

³ At no point in time during any of the hundreds of meet-and-confers that took place in relation to the delineated case management events in this case did Defendants even deign to mention that they would be seeking additional third-party discovery about this topic, despite knowing of Valisure’s citizen’s petition in June of 2019.

1. The Parties conducted *Daubert* briefing and hearings with the Court on issues of General Causation, and the Court issued a ruling on these motions (completed on March 3, 2022);
2. The Parties conducted depositions of the experts submitted in support to (or opposition of), the Plaintiffs' Motion for Class Certification (completed April 30, 2022);
3. The Parties conducted briefing related to the Class Plaintiffs' Motion for Class Certification (completed May 10, 2022);
4. The Plaintiffs conducted additional depositions of ZHP's 30(b)(6) witnesses (completed May 27, 2022);
5. The Parties briefed *Daubert* issues related to the experts submitted in support to (or opposition of) the Plaintiffs' Motion for Class Certification (completed June 16, 2022);
6. The Plaintiffs made a production of documents from Emery Pharmaceuticals (related to Dr. Najafi, one of Plaintiffs' experts) after briefing with the Court and a Motion to Compel (completed August 22, 2022);
7. The Court issued its rulings on the proposed first trial, and set a case management order related to dispositive motions for that trial (issued August 31, 2022);
8. The Parties fully briefed motions related to specific and more narrowly tailored discovery to be propounded on the TPP Plaintiffs (completed October 20, 2022); and
9. The Plaintiffs submitted liability expert reports (October 31, 2022).

Allowing Defendants to subpoena this information at this juncture will result in upending the entire litigation over evidence that is of no probative value or relevance (as discussed *supra* and *infra*). Permitting Defendants to re-open

discovery, when the fact discovery period closed over a year ago (in a case poised for a bellwether trial in a few months), would be unduly burdensome and prejudicial to Plaintiffs (and Valisure) — especially when Defendants knew about Valisure since 2019 and did absolutely nothing about them until December 2022.

ii. Valisure’s Checkered Past Will Require Plaintiffs to Expend Time and Resources and Result in Cognizable Harm

In addition to the reality that Valisure’s testing has no bearing to the case and has in no way been developed in the factual record by any Party, were the Court to permit Defendants to re-open discovery as to Valisure, Plaintiffs will be required to expend tremendous time, money and resources engaging new expert testimony to assess Valisure’s laboratory operations, which have recently come under fire from regulatory agencies. While Defendants characterize Plaintiffs’ skepticism of the testing contained in Valisure’s Citizen Petition as “sow[ing] confusion,” such skepticism is rooted in very real public regulatory actions which call the validity of the findings contained within Valisure’s Citizen Petition into question.

On December 5, 2022, the FDA issued an untitled letter to Valisure, delineating a host of deficiencies that were observed by FDA inspectors related to their NDMA testing (the subject of Defendants’ Valisure Subpoena), including observations that Valisure’s methods for such testing were flawed, that it did not adequately address OOS testing results, that it used instrumentation which did not meet established specifications, and that it failed to exercise appropriate controls.

See 12/5/2022 Valisure Letter (attached as Exhibit G). Indeed, some the same Defendants here have argued in other cases that Valisure’s work is too unreliable even to form an “information or belief” to plead contamination in a complaint at the Rule 12(b)(6) stage, let alone prove it at trial. *See* Case 2:20-cv-02324-MCA-MAH Dkt. No. 132-1 (D.N.J) (Counsel for Teva and Aurobindo arguing that complaint related to contaminated Metformin should be dismissed because the “FDA likewise has called into question the testing methodology utilized by Valisure”).

It is obvious from the full factual record that has been developed in this litigation that neither Plaintiffs nor Defendants intend to rely on any of the testing conducted by Valisure to establish the NDMA levels contained in any of the at-issue product. Valisure’s testing results (and/or their non-compliance with appropriate testing standards), might matter if Valisure were a party in this litigation, or retained as an expert by a party in this litigation to conduct testing. Valisure, however, is neither of those things.

Furthermore, if testing were so important, one would think that Defendants would have conducted some of their own testing of Valsartan for litigation purposes in the last four-plus years of this matter. But they have not. Instead, they stand by their contemporaneous testing prior to this litigation, the results of which formed part of the bases for the FDA recalls of valsartan.

Consequently, should the Court permit Defendants to engage in this speculative fishing expedition of this unrelated entity, Plaintiffs will have no choice but to expend time, energy, and money in retaining experts to assess, analyze, and potentially dispute or discredit certain claims that Defendants might speculatively try to make using this irrelevant information. This puts Plaintiffs at a significant disadvantage, and all for material and information that would arguably be inadmissible in any trial set to occur. Not to mention, Plaintiffs will not have had an opportunity to test Defendants' own fact and expert witnesses with the material.

V. CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court deny the Defendants' motion to compel, and issue a protective order quashing Defendants' Valisure Subpoena.

Dated: January 13, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Layne C. Hilton
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